REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

Rejections under 35 U.S.C. 102

Claims 1-26 have been rejected under 35 U.S.C. 102(e) as being anticipated by Yip et al. (US 6,846,323).

Claims 1-26 relate to methods and devices for treating vulnerable plaque. Vulnerable plaques are defined as plaques prone, in the presence of an appropriate trigger, to events such as ulceration rupture, erosion, or thrombus. It has been found that the rupture-prone (i.e., vulnerable plaques) typically have a thin fibrous cap, numerous inflammatory cells, a substantial lipid core, and few smooth muscle cells. Many of these so-called "vulnerable plaques" do not block the arteries and do not limit the blood flow through the blood vessels or cause any of the symptoms which lead physicians to treat heart disease. On the other hand, much like an abscess, they are ingrained in the arterial wall, so that they are undetectable by traditional methods. It has recently been appreciated that vulnerable plaques which do not limit flow may be particularly dangerous because they can go undetected and then rupture suddenly causing heart attack and death. The vulnerable plaques are more likely to erode or rupture, creating thrombosis and a raw tissue surface that forms scabs. Thus, they may be more dangerous than other plaques that cause angina or shortness of breath, and may be responsible for as much as 60-80% of all heart attacks.

Traditional methods of diagnosing arterial disease, using such as stress tests and angiograms, are inadequate at detecting these vulnerable plaques. They cannot be seen by conventional angiography or fluoroscopy. Therefore, in many instances, this potentially lethal condition goes untreated. At present, methods are being developed which allow a physician to view vulnerable plaque.

The most common treatments for occluded arteries include angioplasty and stenting or CABG (coronary artery bypass grafting). Drug eluting stents have been developed which prevent or reduce restenosis after angioplasty and stenting. These drug eluting stents are

typically coated with an antirestenotic drug which reduces the inflammation and/or proliferation of tissue at the site of the angioplasty.

The treatment of restenosis is different from the treatment of vulnerable plaque. Although both of these diseases are present within the coronary arteries, they are very different diseases, with different structures, different detection methods, and different treatments. The implantable medical devices and methods of the present application can be used to deliver therapeutic agents into the blood stream for local delivery to the walls of the blood vessels downstream of the implantation site to treat the vulnerable plaque. The delivery of the agent locally at the vulnerable plaque site can stabilize the plaque reducing the occurrences of ruptures and healing the raw exposed tissues from a previous rupture.

Yip et al. describes a specific structure for an intravascular stent. Yip et al. describes that the stent can be coated with an agent to prevent or treat restenosis. (Column 19, lines 36-37) Yip et al. describes the agents which can be used to treat restenosis including anti-proliferatives. (Column 18, line 50 – column 19, line 35) Yip et al. does not teach or suggest a method or a device for treating vulnerable plaque. Accordingly, Yip et al. cannot anticipate claims 1-26.

Claims 15-26 have been rejected as anticipated by Castro et al. (US 6,616,765) Castro et al. describes a method of coating stents with therapeutic substances. Castro et al. does not mention vulnerable plaque. Castro et al. mentions treatment of atherosclerotic plaque with angioplasty. (Column 1, line 25) However, Castro et al. clearly does not teach or suggest the use of an expandable medical device to deliver a therapeutic agent for treatment of vulnerable plaque. As describe above with respect to Yip et al., known drug eluting stents are designed for prevention of restenosis which is a separate disease from vulnerable plaque. Therefore, Claims 1-26 cannot be anticipated by Castro et al.

Claims 14 and 25 relate to a method and implantable medical device in which an agent for treatment of vulnerable plaque is delivered primarily luminally and an antirestenotic agent is delivered primarily murally. This directional delivery of two agents in opposite directions to treat vulnerable plaque and restenosis is not taught or suggested by Yip et al. or Castro et al. For this additional reason, Claims 14 and 25 are allowable.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a further telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below. The Commissioner is authorized to charge any fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-3100.

Respectfully submitted,

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